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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,254	08/01/2003	Douglas G. Evans	150-PDD-02-01-US	4792
<div>C.R. Bard, Inc. C/O Portfolio IP P.O. Box 52050 Minneapolis, MN 55402</div>				
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EXAMINER				
WOO, JULIAN W				
ART UNIT			PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/633,254	Applicant(s) EVANS ET AL.	
	Examiner Julian W. Woo	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 27-38, 42 and 117-119 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 27-38, 42, and 117-119 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The Examiner's indication of allowable subject matter in claims 1-4, 27-38, 42, and 117-119 has been reconsidered and is hereby withdrawn in view of the new ground(s) of rejection below. The rejection of claims under 35 U.S.C. 112 is hereby withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 35 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Richmond (4,509,516). Richmond discloses, at least in figures 1-7, an introducer needle including a first flat spatulated section (12), a straight portion (at 16) connected to a distal end of the first spatulated section, a curved portion (e.g. at central portion of 11) connected to a distal end of the straight portion, a second flat spatulated section (13), and a flared section (21) connected to a distal end of the curved portion and connected at its distal end to the first flat spatulated section, the flared section having a cross-sectional profile that covers a cross-sectional profile of the first spatulated section,

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where at least one flat spatulated section has a tip and a constant width portion disposed between the tip and the central portion, an opening (18) formed in that flat spatulated section, where the first flat spatulated section, the flared section, the straight portion, the curved portion, and the second flat spatulated section are integrally formed.

4. Claims 1-4, 27-31, 34, 37, 38, and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Chien (6,336,731). Chien discloses, at least in figures 1-4 and 6 and in col. 2, line 7 to col. 3, line 7 and col. 3, lines 23-36; a system including an introducer needle (4) having a first end (42) and a second end (41), each having a flattened portion with an opening (43 and at the "hook section") therethrough; a handle (1) having a latch mechanism (16 and 17 combined), an implant member (e.g., a "fishing line") having an end and a connector (a "hook") joining an end of the implant member to the second end (41) of the introducer needle, where the needle is curved (e.g., at its tip) and symmetrical (as viewed from the side or the thickness of the needle), where the flattened portion of the first end differs in size and shape from the flattened end of the second portion, and where the needle has a flared section (between 41 and 42) having a cross-sectional profile that is at least as large as the cross-sectional profile of the connector. The introducer needle includes a central portion (at a portion of 42), a first flat spatulated section (41) and a second flat spatulated section (42) integral with the central portion, where the first flat spatulated section has a rounded tip and a constant width portion, where both flat spatulated sections having an opening formed (43 and at the "hook section"), a flared section (between 41 and 42) connecting the first flat spatulated section to the central portion, the flared section having a cross-sectional

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profile that is at least as large as or covers a cross-sectional profile of the first flat spatulated section, where the first and second flat spatulated sections have substantially the same shape (i.e., one prong of 42 and 41 each have a rectangular shape), where the needle has an asymmetric shape (along its width), where each of the spatulated sections has a tip, and the tip of the first spatulated section has first configuration and the tip of the second spatulated section has a second configuration, where the needle is arcuate (e.g., at its tip), where the needle includes a body portion (4) having a proximal straight portion (42) integral with a curved distal portion, a handle (1) receiving the proximal end of the straight portion, the flat spatulated section (41) has a "T"-shaped cavity or opening (at the "hook section") located at the distal end of the curved portion, where the handle is permanently attached to the proximal end of the straight portion (after latching), where the needle includes a flared section (between 41 and 42), and where a leg of the "T" extends to an edge of the flat spatulated section.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chien (6,336,731) in view of Smith et al (4,799,484). Chien discloses the invention substantially as claimed, but does not disclose that the central portion has a circular or an oval cross section. Smith et al. teach, in figures 5a and 5b and in col. 2, lines 19-26 and col. 3, line 58 to col. 4, line 14; a needle with a circular or an oval cross section. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Smith et al., to modify at least the central portion of the needle of Chien, so that it has a circular or an oval cross section. Such a configuration would ease the needle's penetration and rotation in tissue or material where the needle is applied.

7. Claims 117-119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chien (6,336,731) in view of Eaton et al. (5,234,436), and further in view of Tzeng et al. (6,005,191). Chien discloses the system substantially as claimed (See the rejection of claim 1 above), but does not disclose that the needle has a shrink-tubing sleeve, where at least a portion of the sleeve is at least one of green and blue or blue. Eaton et al. teach, at least in figures 3A-3D and col. 4, lines 27-36; a needle (e.g., 25) that includes a sleeve (28) made of pliable plastic or silicone rubber, but Eaton et al. do not teach that the sleeve is formed of shrink-tubing or has the color as claimed. Tzeng et al. teach, at least in col. 5, line 37 to col. 6, line 14; that shrink-tubing can be formed of pliable plastic (i.e., polymeric materials) or silicone rubber. Thus, it would have been obvious to one

having ordinary skill in the art at the time the invention was made, in view of Eaton et al. and Tzeng et al., to include a shrink-tubing sleeve (made of a pliable plastic or silicone rubber) with the needle of Chien. Such a sleeve would conform to and protect the surfaces of the needle and would prevent undue hooking of material at the "hook section" of the needle before use of the system. Regarding the color of the sleeve: It would have been obvious to one having ordinary skill in the art to apply a color as claimed in the sleeve of Chien in view of Eaton et al. and Tzeng et al., since it has been held to be within the general skill of a worker in the art to select a known material (and its color) for the sleeve on the basis of its suitability for the intended use as a matter of obvious design choice.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cunningham (7,063,716) teaches a needle that can have various cross-sections.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

September 14, 2007